

REMARKS

No amendments or cancellations are made to the claims in the Applicant's current response. A listing of the claims has been provided which is believed to reflect only the status of the claims as amended in the Applicant's prior response. Claims 45-51 and 136-145 remain in this application and are believed to be in a condition for allowance.

Included with the Applicant's current response is an Information Disclosure Statement. Although the Information Disclosure Statement provides additional information for the Office to consider, such information possibly may be material to patentability and accordingly the Information Disclosure Statement is believed to be the only means for the Applicant to comply with its duties under 37 C.F.R. § 1.56.

The Applicant notes that much of the current Office Action appears to mirror the discussion raised in prior Office Actions in the current case. Moreover, a specific response to the submissions made by the Applicant in its Response and Request for Reconsideration dated January 13, 2005, appear to have been addressed in the current Office Action in the text marked as "Response to Arguments". Accordingly, it is believed that addressing the discussion contained in the "Response to Arguments" will fully respond to the issues raised in the current Office Action.

As a preliminary matter, the Applicant notes that many of the issues and concerns related to the present case present complex and intertwining considerations. Accordingly, in the event questions remain, the Applicant requests the opportunity to pursue an interview to resolve any issues or concerns.

With regard to the combination of Rens, Wilhelm, and Rath, the Applicant disagrees with the obviousness concerns raised in the Office Action. The Office states that the Applicant in its January 13, 2005 response argued that Rens does not specifically exemplify applying the sorting method to equine sperm. This is not an accurate

characterization of the Applicant's argument. Rather, at pages 9-10 of the prior response, the Applicant has pointed out that Wilhelm – not Rens – nowhere indicates that equine sperm are used for artificial insemination. Rather, the use to which Wilhelm puts equine sperm is to determine if certain kinds of liposomes protect equine sperm from damage during cooling and freezing processes, a purpose completely different from artificial insemination. Accordingly, it is the combination of references – not each reference individually – that do not teach sorting equine sperm for artificial insemination. The omission of this teaching is significant. This is because one of the three requirements the Office has for establishing a *prima facie* case of obviousness is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. MPEP § 2143. Here, such a suggestion is not made explicitly by the references. Moreover, such a suggestion cannot be presumed to have come from the knowledge generally available to one of ordinary skill in the art. This is because, as pointed out by the Applicant in its prior response, there are numerous difficulties associated with sorting equine sperm cells that would have dissuaded an artisan at the time of the instant invention from combining the references as proposed by the Office. To reiterate, the specification at page 2, lines 26-28, discusses that natural insemination for equines involves billions of sperm and page 3, lines 1-4 discusses that conventional techniques for equine artificial insemination routinely use 250 million to 500 million sperm. At page 2, lines 15-19, the specification relates that flow cytometry techniques as of the time of the invention produce adequate numbers of sorted sperm in a reasonable amount of time for many species other than equines, including cattle. However, as discussed in the specification at page 2, lines 7-8, to make semen sexing a practical technique for equines, a lesser number of motile sperm is required for an insemination dose. Further, as discussed in the specification at page 4, lines 20-23, the equine conception process and/or the equine sperm cells themselves are more delicate than those of other species – especially bovines. In the context of flow cytometry, as discussed in the specification at page 5, lines 16-29, most sorted cells are able to physically withstand a variety of abuses. However, this is not the case for equine sperm cells, which may exhibit sensitivities to factors ranging from dilution problems to

pressure stresses to the flow cytometer's need to distinguish each cell individually. As a result, this may represent a unique factor for equine sperm cells because flow cytometric sorting may have stressed the cells to the point of suboptimal performance, even though no visually discernable side-effects are displayed. Moreover, because the Applicant has showed why combining the references in the manner suggested by the Office would not have been obvious, it is not sufficient to assert, as was done in the Office Action, that the references taken collectively would have led one of ordinary skill in the art to the claimed method in which the sorting process of Rens was applied to equine sperm. A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. MPEP § 2143.01; *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). Accordingly, it is the Office's responsibility to provide an objective reason for combining the references beyond merely that aspects of the claimed invention may have been individually known.

Regarding the use of skim milk solutions taught by Wilhelm, the Applicant disagrees with the obviousness concerns raised in the Office Action. The Office states that Applicant's arguments are directed to the individual references and the fact that the references taken individually do not teach the claimed invention. Again, this is not an accurate characterization of the Applicant's argument. As discussed on pages 10-11 of the Applicant's prior response, the Applicant's argument focuses on the combination of references desired by the Office and the fact that the suggestion or motivation to combine these references as required by MPEP §2143 does not exist. It is true the Applicant has discussed individual aspects of the references – notably, that Wilhelm teaches no artificial insemination techniques and uses skim milk only for freezing applications, and that Rath teaches only collecting sorted sperm into a TEST extender. However, such discussion of the references individually is merely to point out that if the Office wishes to combine them, the Office must provide the suggestion or motivation required by MPEP

§2143. The Office has not provided this. Again, such a suggestion or motivation must be either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Here, the Office does not appear to assert such a suggestion or motivation exists in the references themselves. Moreover, such a suggestion cannot be presumed to have come from the knowledge generally available to one of ordinary skill in the art. The Office asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have collected the sorted sperm in the skim milk solution of Wilhelm because this would have provided an effective medium for protecting the equine sorted sperm. However, this ignores the facts that Wilhelm teaches skim milk solutions for freezing applications only – recall that Wilhelm itself affirmatively refers to SMEY as a “freezing extender”, *see e.g.* the Wilhelm abstract – and that Wilhelm teaches no artificial insemination techniques. As such, the ordinary artisan would only have recognized that Wilhelm’s use of a skim milk solution would have provided an effective medium for protecting equine sperm in a *freezing* application. While it may be true as asserted by the Office that the ordinary artisan would have recognized that alternative extender solutions could also be used to *collect* the sorted sperm, the reach of this statement is valid only insofar as it extends – *i.e.* to the artisan’s search for extenders used for similar *collection* purposes. The Office has presented no evidence that an ordinary artisan would look to extenders used for different purposes entirely – *i.e.*, *freezing* extenders. Stated differently, Rath teaches the use of extenders for one purpose, *collecting* sorted sperm, while Wilhelm teaches the use of extenders for different purposes, *freezing* sperm, and the Office has not demonstrated that the ordinary artisan would have bridged the conceptual difference separating these two purposes in order to combine the teachings of Rath and Wilhelm. Accordingly, the Office has failed to carry its burden under MPEP § 2143.01 and *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993), requiring some objective reason to combine the teachings of the references. Moreover, while it is true that under *Ex parte Obiaya*, 227 U.S.P.Q. 58, 60 (Bd. Pat. App. & Inter. 1985), the motivation to combine references need not be the same as those disclosed by Applicants, the only combination suggested by the references cited by the Office would be to use a skim milk solution to *freeze* equine sperm. As discussed above, these references do not provide a suggestion or motivation to

combine Rath and Wilhelm to use a skim milk solution to *collect* sorted equine sperm, nor indeed even to combine Rens and Wilhelm to *sort* equine sperm due to the practical difficulties of doing so at the time of the invention.

With respect to the fact that the combination of Rens, Wilhelm, and Rath does not provide a reasonable expectation of success, the Office asks if the known flow cytometers conventionally used in the art cannot be used with the present invention, then what flow cytometer may be used? However, the Applicant's argument in the prior response did not assert that flow cytometers known at the time of the invention were not fast enough to sort the required number of sperm cells, but rather that they could not do so *while maintaining sperm viability*. As discussed in the specification at page 5, lines 8-29, equine sperm cells are particularly delicate and normal flow cytometry sorting techniques accordingly may be unacceptable for equine sperm cells. The specification at page 19, lines 25-29 and page 20, lines 1-11 further describes how high speed operation of a flow cytometer may contribute stresses that may adversely affect sperm cells. Moreover, such high speed sorting is particularly necessary for equine sperm cells given the numbers of equine sperm cells required for successful artificial insemination, as described in the specification at page 2, lines 3-25. Accordingly, as described in the specification at page 20, lines 12-30 and page 21, lines 1-3, the present invention teaches techniques that minimize the stresses associated with high speed flow cytometer sorting of equine sperm cells. With attention to Rens and Rath, flow cytometry is used to separate bovine and porcine sperm, which does not involve the use of high speed operation of a flow cytometer as is the case for equine sperm. Moreover, high speed sorting was a problem beyond the ordinary skill in the art at the time of the invention, because it would require from the ordinary artisan more inventive effort than merely determining the optimum quantities and volumes for an equine artificial insemination sample. Therefore, with respect to the references cited and the ordinary skill in the art, only the present case teaches techniques that allow for successful equine artificial insemination with low numbers of equine sperm, which makes possible the use of flow cytometry to separate sperm in equine applications. Accordingly, while Rens and Rath may suggest that it would be desirable to use flow cytometry in an equine context, they

do not teach techniques for accomplishing this goal and therefore suggest only that it would be obvious to try, as described in *In Re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Accordingly, combining Rens and Rath would not provide one of ordinary skill in the art a reasonable expectation of success at the time the invention was made, as required by MPEP § 2143.02.

With respect to the Catt reference, the Applicant disagrees with the obviousness concerns raised in the Office Action. The Office attempts to combine Catt with Rens, Wilhelm, and Rath. However, as discussed above, to achieve such a combination there must be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. MPEP § 2143. Such a suggestion or motivation has not been provided by the Office to the required standard. The Office does not appear to assert the references themselves suggest such a combination. Moreover, such a suggestion or motivation cannot be presumed to come from the knowledge generally available to one of ordinary skill in the art. To have achieved the combination with Catt, an ordinary artisan would have been required to take two inventive steps. First, the knowledge in the art at the time of the invention actually suggested against using a HEPES-buffered medium for equine sperm. As pointed out in Applicant's prior response and discussed in the specification at page 20, lines 26-30 and page 21, lines 1-3, this is evidenced by the fact that the HEPES-buffered medium originally was developed for bovine applications. In assessing obviousness, the totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. MPEP § 2145 X.D.3; *In re Hedges*, 783 F.2d 1038 (Fed. Cir. 1986). Second, even if an artisan had recognized, despite this prevailing view, that a HEPES-buffered medium could be used for equine sperm cells in the dilution capacity taught by Catt, the artisan would still be required to make the additional inventive step of using the HEPES-buffered medium not merely as a diluent, but rather as a sheath fluid. It is the present invention that is the first to recognize that a HEPES-buffered medium confers a particular advantage when used as a sheath fluid for equine applications. Indeed, the specification at page 20, lines 12-30 and page 21, lines 1-3 points out the benefits of

chemically coordinating a sheath fluid with both pre-sort and post-sort chemical environments to minimize stresses to sperm cells within a flow cytometer itself, and notes that a HEPES-buffered medium may work particularly well in this role. Accordingly, the mere fact that the sum of the references teaches sheath fluids, equine sperm cells, and HEPES-buffered media is not sufficient for supporting the conclusion reached by the Office that combining these elements would have been within the ordinary skill in the art. Because the Applicant has shown why combining the references in the manner suggested by the Office would not have been obvious, it is not sufficient to assert, as was done in the Office Action, that the references taken collectively would have led one of ordinary skill in the art to the claimed method in which Catt's use of HEPES-buffered media for dilution purposes was applied to the sheath fluid used to sort equine sperm. A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. MPEP § 2143.01; *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). Accordingly, it is the Office's responsibility to provide an objective reason for combining the references beyond merely that aspects of the claimed invention may have been individually known.

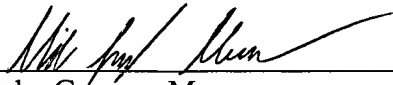
With respect to the combination of Seidel, Wilhelm, and Rath, the Applicant has reviewed the aspects of Seidel called out in the current Office Action. However, notwithstanding the same, it is believed the reasons set forth in this response remain equally applicable to the cited combinations including Seidel. Specifically, such reasons of the Applicant are directed against the applicability of Wilhelm and Rath. Understandably, the removal of Wilhelm and Rath negates their contribution to the combination with Seidel, and therefore such a combination no longer raises an obviousness issue.

With respect to the remaining issues raised in the Office Action, the Applicant disagrees with the issues raised. In particular, with respect to the recitation of about 4% egg yolk, the Applicant notes that such recitation cannot be reasonably considered to encompass 2% egg yolk, in as much as the about 4% egg yolk value essentially is twice that of the cited 2% egg yolk value. In addition, with respect to the operation of a flow cytometer at at least 50 psi, the Applicant notes that because operation of a flow cytometer at such high pressures was known to be detrimental to sperm cells – especially equine sperm cells, which, as discussed, exhibit a particularly delicate nature – therefore it was not appreciated that a flow cytometer could be operated at such high pressures without the benefits of the stress minimization aspects to equine sperm cells taught first by the current invention. Such stress minimization aspects represent an inventive step beyond the mere routine experimentation asserted by the current Office Action as being all that is required. However, the Applicant notes that the remaining issues appear to be directed to dependent claims. The Applicant believes these dependent claims are allowable as depending from the independent claims which the Applicant has shown to be allowable as set forth in this response.

The Applicant, having addressed each of the concerns raised in the Office Action, respectfully requests reconsideration and withdrawal of the rejections and objections to the application. Allowance of claims 45-51 and 136-145 is requested at the Office's earliest convenience.

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Respectfully submitted,
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